

MAY 27 1997

K971204
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Summary of Safety and Effectiveness
LSVP International Hot Biopsy Forceps

Device Name: LSVP International Hot Biopsy Forceps

Common/Usual Name: Hot Biopsy Forceps

Classification Name: Gastroenterology urology biopsy instruments (Class II, Tier 2)

Predicate Devices: Reusable Hot Biopsy Forceps manufactured by Olympus, by Microvasive Corp., by Fujinon, Inc., and by Mill-Rose Labs.

Submitted by: Ms. Sophia Pesotchinsky
(contact person) LSVP International, Inc.
12755 Alto Verde Lane
Los Altos Hills,
Telephone: (415) 917-8100
FAX: (415) 948-7822

Summary Preparation Date: March 27, 1997

Statement of Intended Use: The LSVP International, Inc. Hot Biopsy Forceps are intended for simultaneous biopsy and coagulation of diminutive polyps. Hot biopsy forceps are intended for use in conjunction with an electrocautery unit.

Comparison to Predicate Devices: The LSVP International, Inc., Reusable Hot Biopsy Forceps are similar in design, function, and intended use to the currently marketed reusable Olympus hot biopsy forceps.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 27 1997

Ms. Sophia Pesotchinsky
Vice President, Regulatory Affairs
LSVP International, Inc.
12755 Alto Verde Lane
Los Altos Hills, California 94022

Re: K971204
LSVP International Hot Biopsy Forceps
Dated: April 14, 1997
Received: April 18, 1997
Regulatory class: II
21 CFR §876.4300/Product code: 78 KGE

Dear Ms. Pesotchinsky:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4616. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2. Indication for use statement

510(k) number K971204

Device name: LSVP International Hot Biopsy Forceps

INDICATION FOR USE:

The primary indication for hot biopsy forceps is simultaneous biopsy and coagulation of diminutive polyps.

Hot biopsy forceps are intended for use in conjunction with an electrocautery unit.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert R. Sedberry
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices

Prescription Use ☒
(Per 21 CFR 801.109)

510(k) Number K971204
OR

Over-The-Counter Use ☐

(Optional Format 1-2-96)